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Amendments to the Drawings

Enclosed herewith are corrected drawings consisting of a new sheet depicting Fig. 1, Fig. 1A and new Fig. 1B, and a replacement sheet depicting Fig. 5a and Fig. 5b. Delivery Device 1 is now identified in Figs. 1A and 1B. Compartments 26a through 26e are now also identified in the Replacement Sheet depicting Figs. 5a and 5b. Fig. 1B shows the delivery device 1 inserted into the eye through an incision until the rim of cap 8 abuts the incision.

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REMARKS

Claims 68-129 are pending in the subject application. Claims 68, 79, 83, 93, 99, 108, 111, 116, 121, 122, 126, and 129 are amended herein, claim 128 is canceled, without prejudice, and claims 130-137 are added. Applicants submit that the amendments herein introduce no new matter, support therefore being found throughout the application and drawings as originally filed (see, e.g., paragraph [0037] and Figs. 1, 1a, 2a, 2c, 3a-3c, and 5a-5b). Favorable reconsideration in light of the amendments and remarks which follow is respectfully requested.

1. Oath/Declaration

The Examiner has requested a new oath or declaration, because currently it does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56. Applicants will submit the new declaration to the Patent Office in due course.

2. Drawings

The Examiner objects to the drawings for failing to include reference signs 1, 26c, 26d, and 26e. Enclosed herewith are corrected drawings consisting of a new sheet depicting Fig. 1, Fig. 1A and new Fig. 1B, and a replacement sheet depicting Fig. 5a and Fig. 5b. Delivery device 1 is now identified in Figs. 1A and 1B. Compartments 26a through 26e are now also identified in the Replacement Sheet depicting Figs. 5a and 5b.

The Examiner further objects that the drawings as not showing the cap element sized to prevent the cap element from passing through an incision where the cap element abuts the incision or where the cap element mates against the patient eye outer surface. Enclosed herewith is a corrected drawing consisting of a new sheet depicting Fig. 1, Fig. 1A and new Fig. 1B. Fig. 1B shows the delivery device 1 inserted into the eye through an incision until the rim of cap 8 abuts the incision. Applicants submit that no new matter is introduced by the inclusion of Fig. 1B, support for the contents therein being found at least in paragraphs [0044]-[0045] of the Specification.

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3. Specification

Applicants have amended the abstract to correct typographical errors, as requested. As requested, paragraph 1 of the specification has been amended to set forth corresponding issued U.S. Patent No. 6,719,750. In addition, the Office's attention is directed to related co-pending U.S. patent application no. 10/823,089, currently under a non-final Office Action. The specification has further been amended to include brief descriptions of Figs. 1a, 4b-1, 4c-1, 4d-1, 4d-2 and 5c.

The Office asserts that "[t]he specification fails to disclose the cap element being sized to prevent the cap element from passing through an incision where the cap element abuts the incision or where the cap element mates against the patient eye outer surface. The specification also fails to disclose the body member being in contact with intravitreal fluid." Applicants respectfully traverse this objection.

The specification discloses the relationship of the cap to the incision and its relative size in at least the following passages. It states that the delivery device 1 preferably "is inserted into the eye through an incision until the rim or cap 8 abuts the incision." (paragraph [0044]). In addition, "[t]he rim or cap 8 is designed such that it remains outside the eye and, as such, the rim or cap 8 is sized so that it will not pass into the eye through the opening in the eye through which the device is inserted." (paragraph [0045]). These passages clearly disclose the information requested by the Office.

Regarding contact by the body member with intravitreal fluid, the specification discloses that the "[t]he present invention provides methods and devices for the intraocular delivery of substances ..." (paragraph [0009]) wherein the non-linear or coil-shaped geometry of the body provides a "large intravitreal surface area" (paragraph [0036]-[0037]). Thus the specification clearly discloses that the body member is in contact with intravitreal fluid.

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4. Claim Objections

Claims 108, 116, and 121-128 have been objected to. Applicants have amended the claims as requested by the Office.

5. 35 U.S.C. §112 Rejections

Claim 108 is rejected under 35 U.S.C. §112, second paragraph. Applicants have amended claim 108 as requested. Applicants respectfully request reconsideration and withdrawal of the rejection.

6. 35 U.S.C. §102 Rejections

Rosenman et al.

Claims 68-91, 111-116, and 129 are rejected under 35 U.S.C. 102(c) over U.S. Patent No. 6,478,776 to Rosenman et al. ("Rosenman"). Applicants respectfully traverse.

Applicants recite implantable delivery devices in independent claims 68, 79, 111, 116, and 129. According to claim 68, the device comprises a non linear shaped body member that has a coil or zig-zag shape and a cap element sized to provide a cross-section larger than the cross-section of the coil or zig-zag shape, wherein the cap element abuts the incision to stabilize the device once implanted. According to claim 79, the device comprises a coil-shaped body member and a cap element sized to provide a cross-section larger than the cross-section of the coil-shaped body member, wherein the cap element abuts the incision to stabilize the device once implanted. According to claim 111, the device comprises a coil-shaped body member and a cap element sized to provide a cross-section larger than the cross-section of the coil-shaped body member, wherein the cap element mates against the patient eye outer surface while the body member is inserted to the eye. According to claim 116, the device comprises a non-linear shaped body member that has a coil or zig-zag shape and a cap element sized to provide a cross-section larger than the cross-section of the coil or zig-zag shape, wherein the cap element is configured to mate against the patient eye outer surface while the body member is inserted to the eye. According to claim 129, the device comprises a coil-shaped body member and a cap element sized to provide a

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cross-section larger than the cross-section of the coil-shaped body member, wherein the cap element is in contact with the coil-shaped body member.

Applicants further recite methods for treating a patient using a delivery device. According to claim 83, the method comprises (a) providing a delivery device comprising a non-linear shaped body member that has a coil or zig-zag shape, the body member having a proximal end and a distal end, and a cap element at the proximal end, (b) inserting into a patient through an incision the device whereby the body member resides in the patient and the cap element remains outside the incision through which the device is inserted and abuts the incision to stabilize the device; and (c) allowing a therapeutic substance to be administered to the patient via the body member. According to claim 93, the method comprises (a) providing a drug delivery device comprising a coil-shaped body member and a cap element sized to provide a cross-section larger than the cross-section of the coil-shaped body member, (b) inserting into a patient eye the device whereby the coil-shaped body member is placed in the patient eye and the cap element remains outside the eye and abuts the incision, and (c) allowing a substance to be delivered by the device to the patient. According to claim 99, the method comprises (a) providing a drug delivery device comprising a non-linear shaped body member having a coil or zig-zag shape and a cap element sized to provide a cross-section larger than the coil or zig-zag shape, (b) inserting into a patient eye the device whereby the body member resides in the patient eye and the cap element remains outside the eye and abuts the incision, and (c) administering a substance to the patient via the body member.

The Office points to Rosenman's Figs. 18-19 and asserts that Rosenman discloses an implantable drug delivery device having a cap element (56). Clearly, however, Rosenman's cap element (56) is not sized to provide a cross-section larger than the cross-section of Rosenman's helix 12. Further, Rosenman clearly does not teach or suggest a method wherein a device comprising a non-linear shaped body member having a coil or zig-zag shape and a cap element sized to provide a cross-section larger than the coil or zig-zag shape is inserted into the eye with the body member residing in the eye and the cap element remaining outside the incision abutting/mating with the incision. Rosenman specifically describes methods wherein a device is

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implanted in the myocardium such that it is disposed completely within the myocardium, with the proximal tip of the device being below the level of the endocardium. (see Rosenman, col. 11, ll. 50-53). According to Rosenman, this is a required feature to prevent therapeutic agents such as drug particles or growth factors from being released into the ventricle of the heart and from there into the systemic arterial circulation, causing unwanted and potentially dangerous effects such as tissue ischemia and embolic events (see Rosenman, col. 3, ll. 51-64).

Thus, claims 68, 79, 83, 93, 99, 111, 116, and 129 are patentable over Rosenman. Claims 69-78, 80-82, 84-92, 94-98, 100-110, 112-115, 117-127, and 130-137 depend from claims 68, 79, 83, 93, 99, 111, 116, and 129, and, thus, also are patentable over Rosenman. Reconsideration and withdrawal of the rejections is respectfully requested.

Altman

Claims 68-91, 111-116, and 129 are rejected under 35 U.S.C. 102(b) over U.S. Patent No. 5,551,427 to Altman ("Altman"). Applicants respectfully traverse.

The Office points to Altman's Figs. 7-11 and col. 9, line 52 – col. 11, line 67, and asserts that Altman discloses an implantable drug delivery device having a cap element (54). Clearly, however, Altman's cap element (54), like Rosenman's is not sized to provide a cross-section larger than the cross-section of Altman's helix 12.

Accordingly, Applicants submit that claims 68, 79, 83, 93, 99, 111, 116, and 129 are patentable over Altman. Claims 69-78, 80-82, 84-92, 94-98, 100-110, 112-115, 117-127, and 130-137 depend from claims 68, 79, 83, 93, 99, 111, 116, and 129, and, thus, also are patentable over Altman. Reconsideration and withdrawal of the rejections is respectfully requested.

Weiner et al.

Claims 68-71, 74-78, 83-86, 89-91, 99-102, 106-109, and 116-120 are rejected under 35 U.S.C. 102(b) over U.S. Patent No. 5,466,233 to Weiner et al. ("Weiner"). Applicants respectfully traverse.

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Weiner at least does not teach or suggest Applicants' delivery devices comprising a coil or zig-zag shaped body member or methods of using such a coil or zig-zag shaped body member.

Accordingly, Applicants submit that claims 68, 79, 83, 93, 99, 111, 116, and 129 are patentable over Weiner. Claims 69-78, 80-82, 84-92, 94-98, 100-110, 112-115, 117-127, and 130-137 depend from claims 68, 79, 83, 93, 99, 111, 116, and 129, and, thus, also are patentable over Weiner. Reconsideration and withdrawal of the rejections is respectfully requested.

7. 35 U.S.C. §103 Rejections

Weiner et al. and Darougar et al.

Claims 72, 73, 79-82, 87, 88, 93-97, 103-105, 111-115, and 129 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiner et al. in view of U.S. Patent No. 5,395,618 to Darougar et al. ("Darougar"). Applicants respectfully traverse.

As set forth above, and as acknowledged by the Office on page 11 of the Office action, Weiner does not teach or suggest delivery devices comprising a coil or zig-zag shaped body member or methods of using such a coil or zig-zag shaped body member. However, the Office points to Darougar, which the Office asserts "discloses an implantable drug delivery device" which comprises a "helical shape or a substantially Z-shape", pointing to Figs. 8 and 12.

Darougar describes, in Fig. 8, a device comprising a cylinder 82 with a "series of screw-type protrusions 86" "provided at intervals along the length of the device 80" (col. 10, lines 60-67). Applicants respectfully submit that this cylinder having screw-type protrusions does not fit within Applicants' description of a coil or zig-zag shaped body member. Darougar further describes, in Fig. 12, "a series of braided segments 113" that are "interconnected along the length of the device 111" (col. 11, lines 39-42). Likewise, this interconnected braided structure does not fit within Applicants' description of a coil or zig-zag shaped body member.

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Still further, Darougar describes an ocular device that is designed for positioning in the upper or lower fornix of the conjunctiva such that it bends along the curvature of the eye within the fornix (see e.g. col. 3, lines 19-26, 54-56; Figs. 5 and 6). In other words, Darougar's device is positioned under the eyelid, between the lid and the globe (see col. 9, lines 13-53). Thus, Darougar's device and methods are very different than those of Applicants' and Weiner's. In particular, Darougar's device is not implanted within the eye through an incision but, rather, it is merely positioned outside of the eye (on the outer surface) between the globe and the eyelid.

Thus, Applicants' respectfully submit that given the different use of Darougar's device as a device that rests between the outer surface of the eye and the eyelid rather than a device that is implanted within the eye intraocularly, there would be no motivation to modify Weiner's device to provide the shape of Darougar's device. Still further, even if Weiner was modified to provide Darougar's shape, Applicants' devices and methods still would not be obtained -- in particular, Darougar does not teach or suggest a coil or zig-zag shape in accordance with Applicants' description.

In view thereof, it is respectfully submitted that claims 68, 79, 83, 93, 99, 111, 116, and 129 are patentable over Weiner and Darougar. Claims 69-78, 80-82, 84-92, 94-98, 100-110, 112-115, 117-127, and 130-137 depend from claims 68, 79, 83, 93, 99, 111, 116, and 129, and, thus, also are patentable over Weiner and Darougar. Reconsideration and withdrawal of the rejections is respectfully requested.

Rosenman et al. and Johnson

Claim 92 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenman et al. and U.S. Patent No. 5,972,027 to Johnson ("Johnson").

As set forth above, Rosenman at least fails to teach or suggest a cap element sized to provide a cross-section larger than the cross-section of the helix 12 or a method wherein a device comprising a non-linear shaped body member having a coil or zig-zag shape and a cap element sized to provide a cross-section larger than the coil or zig-zag shape is inserted into the eye with

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the body member residing in the eye and the cap element remaining outside the incision abutting/mating with the incision.

Johnson is cited for describing shape memory materials. However, Johnson does not remedy the above-noted deficiencies in Rosenman.

Accordingly, claims 68, 79, 83, 93, 99, 111, 116, and 129 are patentable over Rosenman and Johnson. Claims 69-78, 80-82, 84-92, 94-98, 100-110, 112-115, 117-127, and 130-137 depend from claims 68, 79, 83, 93, 99, 111, 116, and 129, and, thus, also are patentable over Rosenman and Johnson. Reconsideration and withdrawal of the rejections is respectfully requested.

Weiner et al., Darougar et al., and Johnson

Claim 98 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weiner in view of Darougar as applied to claim 93, and further in view of Johnson.

As set forth above, given the different use of Darougar's device as a device that rests between the outer surface of the eye and the eyelid rather than a device that is implanted within the eye intraocularly, there would be no motivation to modify Weiner's device to provide the shape of Darougar's device. Still further, even if Weiner was modified to provide Darougar's shape, Applicants' devices and methods still would not be obtained -- in particular, Darougar does not teach or suggest a coil or zig-zag shape in accordance with Applicants' description.

Johnson, which is cited for describing shape memory materials, does not remedy the above-noted deficiencies in Darougar and Weiner.

In view thereof, it is respectfully submitted that claims 68, 79, 83, 93, 99, 111, 116, and 129 are patentable over Weiner, Darougar, and Johnson. Claims 69-78, 80-82, 84-92, 94-98, 100-110, 112-115, 117-127, and 130-137 depend from claims 68, 79, 83, 93, 99, 111, 116, and

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129, and, thus, also are patentable over Weiner, Darougar, and Johnson. Reconsideration and withdrawal of the rejections is respectfully requested.

Weiner et al. and Johnson

Claim 110 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weiner and Johnson. Applicants respectfully traverse.

As set forth above, and as acknowledged by the Office, Weiner does not teach or suggest delivery devices comprising a coil or zig-zag shaped body member or methods of using such a coil or zig-zag shaped body member. Further, Johnson, which is cited for describing shape memory materials, does not remedy the above-noted deficiencies in Weiner.

In view thereof, it is respectfully submitted that claims 68, 79, 83, 93, 99, 111, 116, and 129 are patentable over Weiner and Johnson. Claims 69-78, 80-82, 84-92, 94-98, 100-110, 112-115, 117-127, and 130-137 depend from claims 68, 79, 83, 93, 99, 111, 116, and 129, and, thus, also are patentable over Weiner and Johnson. Reconsideration and withdrawal of the rejections is respectfully requested.

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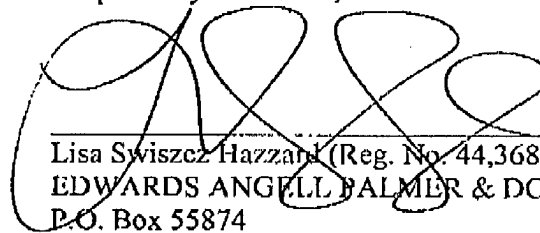
CONCLUSION

In view of the foregoing, applicants request reconsideration and allowance of claims 68-127, and 129-137.

If for any reason the fee paid is inadequate or credit is owed for any excess fee paid, the Office is hereby authorized and requested to charge Deposit Account No. 04-1105.

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Respectfully submitted,



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